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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

April 24, 2002

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 02-44

Charles Bundrant, President
Trident Seafoods Corporation
5303 Shilshole Avenue Northwest
Seattle, Washington 98107-4000

WARNING LETTER

Dear Mr. Bundrant:

We inspected your firm located at 111 Marine Way, Kodiak, Alaska, on March 22, 2002, and found you have a serious deviation from Title 21 of the Code of Federal Regulations (21 CFR) Part 123 - Fish and Fishery Products (Seafood HACCP regulations). A FDA 483 form (copy-enclosed) listing the deviation was presented to Greg D. Hathaway, Plant Manager, at the conclusion of the inspection. This deviation causes your surimi products to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the Seafood HACCP regulations through links in FDA's homepage at www.fda.gov.

The deviation is as follows:

1. You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b). Your firm does not have a HACCP plan for surimi product to control the food safety hazards of allergens and metal inclusion.

This deviation was previously brought to your attention. You were advised that a HACCP plan was necessary to control the food safety hazard of metal inclusion during our inspections of your facility on January 31, 2001, and on July 28, 2001. You were advised that a HACCP plan was necessary to control the food safety of allergens during our inspection of your facility on July 28, 2001. We also advised you of the need to control these food safety hazards through a HACCP plan in our letter to you dated September 20, 2001. We received a letter from Larry Dutton, Vice President, Quality Assurance, stating that the metal hazard had been identified as a hazard through hazard analysis and a "ccp". We sent a letter to Mr. Dutton dated November 26, 2001, stating that he had not submitted the HACCP plan to us for review, so we could not comment on it. We also advised him that our concern regarding the food safety hazard of allergens had not been addressed.

During the inspection our investigator was informed that all second grade surimi product, which is the only product that contains the egg whites, is exported to [redacted] Your firm could not produce documentation to demonstrate that this surimi product met the provisions of section 801(e) of the Act. Exported product that meets the provisions of section 801(e) will not be considered adulterated or misbranded under the Act. As long as your firm does not meet the provisions of section 801(e), it is considered to be in domestic commerce, and therefore, regulated under the Act.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations, and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

We may take further action if you do not promptly correct this violation. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating. In addition, we may not provide certificates to your firm for export of your products to European Union (EU) countries if you do not correct this deviation.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct this deviation. You may wish to include in your response documentation such as your revised HACCP plan and copies of your monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect you will explain the reason for your delay and state when you will correct any remaining deviations.

Please send your reply to the Food and Drug Administration, Attention: Lisa M. Althar, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have questions regarding any issue in this letter, please contact Lisa M. Althar at (425) 483-4940.

Sincerely,

Charles M. Breen
District Director

Enclosures:
Form FDA 483
21 CFR PART 123
Sections 402 and 801(e) of the Federal Food, Drug, and Cosmetic Act